

OCT - 9 2009

510(k) Summary

Regulatory Affairs Contact:

Muhamad Ansari
Busse Hospital Disposables
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Date Summary Prepared:

July 15, 2009

Product Trade Name:

Busse Surgical Drapes III

Common Name:

Busse Surgical Drapes III

Classification Name:

Surgical Drapes III
Class II, 21 CFR 878.4370, Product code KXX

Predicate Device:

Busse Surgical Drapes II, K083424

Device Description:

The Laminated Non-Woven Surgical drapes described in this submission are one piece, single use, designed to provide an absorbent sterile barrier & protection from microbial and other contamination. There are various sizes, with & without fenestration, and with & without adhesive strip/patch.

Intended Use:

A Surgical Drape is a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using ethylene oxide.

Technological Characteristics:

The subject device has the same Technological Characteristics as a legally marketed predicate device

Summary of Testing:

All materials used in the fabrication of the surgical drapes were evaluated through biological qualification safety tests.

The biocompatibility tests performed were:

1. Kligman Maximization Test
2. Intracutaneous Injection Test
3. Systemic Injection Test
4. Rabbit Pyrogen Test
5. L929 Mem Elution Test

These materials have met the testing requirements and were found to be acceptable for the intended use.

Conclusion:

The above statements are accurate representations of the device Busse intends to market. Based on all the testing and comparison Busse believes the subject device is substantially equivalent to the predicate device. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-0609
Silver Spring, MD 20993-0002

Mr. Muhamad Ansari
Director of Regulatory Affairs
Busse Hospital Disposables, Incorporated
75 Arkay Drive
Hauppauge, New York 11788

OCT - 9 2009

Re: K092212
Trade/Device Name: Busse Surgical Drape II
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKK
Dated: September 10, 2009
Received: September 11, 2009

Dear Mr. Ansari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

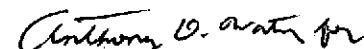
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Susan Ruffner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K092212

Device Name: Busse Surgical Drape III

Indication for Use:

The Busse Surgical Drape is intended to be used as a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using Ethylene Oxide. This is the same intended use as a previously cleared for the Busse Surgical Drape II, K083424. The Drapes included in this submission are the following:

- 687 – Sterile Blue Laminated Non-Woven 22 x 25 Drape with 2 ¼" Fenestration and Adhesive Patch
- 686 – Sterile Blue Laminated Non-Woven 22 x 25 Drape

Prescription Use _____
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X _____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092212